UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,668	02/25/2002	Jorg Breitenbach	480/1240	8161

26474 7590 08/01/2003

KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER	
BENNETT, RACHEL M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

The Office Action that was mailed to you on April 22, 2003 was returned to our office. You filed a change of the address for this application on April 4, 2003 which was never changed in the system. Your response period is set to expire ~~one~~ Three month from the date of this letter.

Brenda L. Gray
Supervisory Legal Instruments Examiner
Technology Center 1600
Team 1694

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,668	02/25/2002	Jorg Breitenbach	480/1240	8161

7590 04/22/2003

Herbert B. Keil
KEIL & WEINKAUF
1101 Connecticut Ave., N.W.
Washington, DC 20036

EXAMINER	
BENNETT, RACHEL M	

ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,668	BREITENBACH ET AL.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- Th MAILING DATE of this communication appears on the cov r sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The examiner acknowledges receipt of Preliminary Amendment A filed 2/25/02 and Information Disclosure Statement filed 7/9/02.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 2/26/01. It is noted, however, that applicant has not filed a certified copy of the 101 09 257.1 application as required by 35 U.S.C. 119(b).

Specification

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of

the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 3-5 recite the broad recitation, and the claim also recites "preferably..." and "particular..." which is the narrower statement of the range/limitation. In the present instance, claim 6 recites the broad recitation, and the claim also recites "particular..." and "e.g...." which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breitenbach et al. (US 6221638 B1).

Applicants claim a solid formulation based on lipoid acid and where appropriate, other active substances and a formulation base having a binder component and where appropriate other excipients, wherein lipoid acid is in the form of a molecular dispersion.

Breitenbach discloses a process for producing solid dose forms by mixing at least one polymeric binder, with or without at least one active ingredient and with or without conventional additives, and shaping the mixture, where at least one of the components is employed in liquid form. See abstract. The dose forms obtainable generally comprise: a) from 0 to 100% by weight, in particular from 0.1 to 50% by weight of an active ingredient, b) from 0 to 100% by

weight in particular from 50 to 99.9% by weight of a polymeric binder and c) with or without additives. Particularly suitable binders are pharmacologically acceptable polymers. See col. 2 lines 13-39. The polymeric binder is preferably employed in the form of an aqueous or alcoholic dispersion or solution. See col. 2 lines 40-48. The dispersions are preferably prepared using physiologically tolerated emulsifiers or protective colloids as dispersants. Examples include cellulose derivatives, polyvinylpyrrolidone or copolymers containing vinylpyrrolidone. Further useful binders include cellulose derivatives such as cellulose esters and cellulose ethers. See col. 4. The amount of active ingredient per dose unit and the concentration can each be varied within wide limits depending on efficacy and rate of release. The sole condition is that they are sufficient to attain the desired effect. Thus, the concentration of active ingredient can be in particular in the range from 0.1 to 95, preferably from 20-80 and especially from 30 to 70% by weight. Combinations of active ingredients can also be employed. Active ingredients can be vitamins and mineral substances. The vitamins include vitamins of the A group, and the B group, including lipoic acid. See col. 6, lines 38-58. Breitenbach does not specifically disclose lipoic acid in a specific example

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used lipoic acid the solid dosage form taught by Breitenbach because Breitenbach teaches lipoic acid may be used as the active ingredient. Furthermore, Breitenbach also teaches lipoic acid may be used in combination with other active ingredients.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sarlikiotis et al. (US 5527539) discloses a drug formulation in the form of tablets

containing thioctic acid (alpha-lipoic acid) with an active ingredient content between 45% by weight and 99.9% by weight. See abstract. All pharmaceutically common binders, such as cellulose derivatives, polyvinyl pyrrolidone, vinylpyrrolidone-vinyl acetate copolymer may be used. The binders can be introduced into the granulation liquid dissolved or dispersed. Kotherade et al. (US 6423256) discloses a process for producing solid dosage forms. Hettche et al. discloses dosage forms of thioctic acid. Ashida et al. (US 5994324) discloses a water soluble vitamin composition.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett
April 17, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600